10/081165

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Patent of:

DEKKER

Patent No.: 6,896,661 B2

Issued: May 24, 2005

Confirmation No.: 8432

Atty. File No.: 41942-04510

For: "MONITORING PHYSIOLOGICAL PARAMETERS BASED ON VARIATIONS IN A PHOTO-PLETHYSMOGRAPHIC BASELINE SIGNAL"

REQUEST FOR CERTIFICATE OF CORRECTION OF PATENT FOR PTO MISTAKE
(37 C.F.R. 1.322(a))

Certificate
JUN 27 2005
of Correction

CERTIFICATE OF MAILING

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450 ON 6-15-05

MARSH FISCHMANN & BREYFOGLE LLP

BY: Dalene Berg

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is a request for a Certificate of Correction for PTO mistake under 37 C.F.R. 1.322(a). The errors in the patent are obvious typographical errors or omissions and the correct wording can be found in the Amendment and Response dated October 21, 2003, at Page 7, line 9. Attached is form PTO 1050 in duplicate along with copies of documentation that unequivocally supports patentee's assertion(s).

Also, this is a request in relation to the above-identified U.S. Patent for issuance of a Certificate of Correction for Applicant's mistake. The errors in the patent are obvious typographical errors. Attached in duplicate is form PTO 1050 and a check in the amount of $100.00 to cover the

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fee set forth in 37 C.F.R. Section 1.20(a). Please credit any over-payment or debit any underpayment to Deposit Account No. 50-1419.

Respectfully submitted,

MARSH FISCHMANN & BREYFOGLE LLP

By: _____

Russell T. Manning
Registration No. 51,260
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Date: 6/15/05

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 6,896,661 B2
DATED : May 24, 2005
INVENTOR(S): DEKKER

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Column 13
Line 8, delete "transmittal", and insert therefor --transmitted--;
Line 10, delete "detective", and insert therefor --detected--; and
Line 20, delete "laid", and insert therefor --said--.

MAILING ADDRESS OF SENDER:
Russell T. Manning, Esq.
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720-406-0506

PATENT NO. 6,896,661 B2

FORM PTO-1050

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:

DEKKER, Andreas L.

Serial No.: 10/081,165

Filed: February 22, 2002

Confirmation No.: 8432

Atty. File No.: 41942-04510

For: "MONITORING PHYSIOLOGICAL PARAMETERS BASED ON VARIATIONS IN A PHOTOPLETHYSMOGRAPHIC BASELINE SIGNAL"

Group Art Unit: 3736

Examiner: MALLARI, Patricia C.

AMENDMENT AND RESPONSE

CERTIFICATE OF MAILING

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450 ON October 21, 2003

MARSH FISCHMANN & BREYFOGLE, LLP

BY: Bobbye D. Simon

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicant submits this Amendment and Response to address the Office Action having a mailing date of May 21, 2003. Enclosed herewith is a petition for a two-month extension of time, thereby extending the time period for response from August 21, 2003 to October 21, 2003. Also enclosed is a check in the amount of $632.00 which includes $420.00 for the extension fee and $212.00 for the additional claims presented herein. Please credit any overpayment or charge any underpayment to Deposit Account No. 50-1419.

Please amend the above-identified patent application as follows:

IN THE CLAIMS:

1. (Currently Amended) A method for use in noninvasively monitoring a physiological parameter of a patient, comprising the steps of:

obtaining a photoplethysmographic ("pleth") signal that is modulated based on interaction of a transmitted optical signal with blood of said patient, wherein said pleth signal includes at least a first respiratory component ~~associated with the operation of the patient's respiratory system~~ and a second Mayer wave component associated with the patient's autonomic nervous system;

processing said pleth signal relative to said first and second components to distinguish ~~an~~ effects associated with ~~one of~~ said first respiratory component ~~and second components from an effect~~ from effects associated with ~~the other of~~ said second Mayer wave components; and

~~using said distinguished effect to~~ monitoring said physiological parameter using at least one said distinguished effect.

2. (Original) A method as set forth in Claim 1, wherein said first component relates to the patient's respiratory sinus arrhythmia.

3. Canceled.

4. (Original) A method as set forth in Claim 1, wherein said step of obtaining comprises the substeps of:

providing at least one source for transmitting an optical signal;

operating said at least one source to transmit said optical signal relative to said patient such that said signal interacts with said blood of said patient;

providing a detector system and generating said detector system to detect said transmitted optical signal and provide said pleth signal reflective of said detected optical signal; and

providing a processor and operating said processor to obtain said pleth signal.

5. (Original) A method as set forth in Claim 4, wherein said substep of providing at least one source comprises providing two sources having different spectral contents.

6. (Original) A method as set forth in Claim 1, wherein said step of processing comprises the substep of distinguishing an effect associated with said first component and said step of using comprises the substep of monitoring said patient's breathing.

7. (Original) A method as set forth in Claim 6, wherein said substep of distinguishing comprises using said pleth signal to monitor information related to both blood pressure and heart rate.

8. (Currently Amended) A method as set forth in Claim 7, wherein said monitoring information related to blood pressure step ~~is monitored by~~ comprises acquiring at least a portion of the pleth signal, filtering at least one component from the acquired signal portion, and determining information regarding a variation in blood volume over time related to the first and second components.

9. (Currently Amended) A method as set forth in Claim 7, wherein said monitoring information related to heart rate step ~~is monitored by~~ comprises acquiring at least a pulsatile portion of the pleth signal and determining information regarding a variation in heart rate over time related to the first and second components.

10. (Original) A method as set forth in Claim 6, wherein said substep of distinguishing comprises determining first information related to a first signal defined by variations in blood pressure over time, determining second information related to a second signal defined by variations in heart rate over time, and using said first information and said second information to obtain third information related to a phase difference between said first signal and said second signal.

11. (Original) A method as set forth in Claim 10, wherein said substep of distinguishing further comprises using said identified phase difference to analyze said pleth signal so as to obtain information related to said first component.

12. (Original) A method as set forth in Claim 6, wherein said substep of distinguishing comprises determining first information related to a first signal defined by variations in blood pressure over time, determining second information related to a second signal defined by variations in heart rate over time, and using said first information and said second information to obtain third information related to a difference in waveform between said first signal and said second signal.

13. (Original) A method as set forth in Claim 6, wherein said substep of monitoring comprises measuring said patient's respiration rate.

14. (Currently Amended) A method for use in monitoring a patient's breathing comprising the steps of:

transmitting an optical signal relative to said patient such that said signal interacts with blood of said patient;

operating a detector system to detect said transmitted optical signal and provide a photoplethysmographic ("pleth") signal reflective of said detected optical signal, where said pleth signal includes at least a first respiratory component ~~associated with the operation of the patient's respiratory system~~ and a second Mayer wave component associated with the patient's autonomic nervous system;

first processing said pleth signal to isolate a pulsatile pleth signal and a baseline pleth signal;

second processing said baseline pleth signal to distinguish ~~an~~ effects associated with the said first respiratory component from effects associated with said second Mayer wave component; and

using said distinguished effects to monitor said patient's breathing.

15. (Original) A method as set forth in Claim 14, wherein said first component relates to the patient's respiratory sinus arrhythmia.

16. Canceled.

17. (Original) A method as set forth in Claim 14, wherein said step of transmitting comprises operating one or more sources to provide a first channel of said signal having a first spectral content and a second channel of said optical signal having a second spectral content different from said first spectral content.

18. (Currently Amended) A method as set forth in Claim 14, wherein said step of distinguishing comprises using said baseline ~~pleth~~ signal to monitor information related to one of blood pressure and heart rate.

19. (Currently Amended) A method as set forth in Claim 18, wherein said monitoring information related to blood pressure step ~~is monitored by~~ comprises acquiring at least a portion of the baseline ~~pleth~~ signal, filtering at least one component from the acquired signal portion and determining information regarding a variation in blood volume over time related to the first and second components.

20. (Currently Amended) A method as set forth in Claim 18, wherein said monitoring information related to heart rate step ~~is monitored by~~ further comprises acquiring at least a pulsatile portion of the pleth signal and determining information regarding a variation in heart rate over time related to the first and second components.

21. (Original) A method as set forth in Claim 14, wherein said step of distinguishing comprises determining first information related to a first signal defined by variations in blood pressure over time, determining second information related to a second signal defined by variations in heart rate over time, and using said first information and said second information to obtain third information related to a phase difference between said first signal and said second signal.

22. (Original) A method as set forth in Claim 21, wherein said step of distinguishing further comprises using said identified phase difference to analyze said pleth signal so as to obtain information related to said first component.

23. (Original) A method as set forth in Claim 14, wherein said substep of distinguishing comprises determining first information related to a first signal defined by variations in blood pressure over time, determining second information related to a second signal defined by variations in heart rate over time, and using said first information and said second information to obtain third information related to a difference in waveform between said first signal and said second signal.

24. (Original) A method as set forth in Claim 14, wherein said substep of monitoring comprises measuring said patient's respiration rate.

25. (Currently Amended) An apparatus for use in monitoring a patient's breathing, comprising:

a port for receiving a photoplethysmographic ("pleth") signal that is modulated based on interaction of a transmitted optical signal with blood of said patient, wherein said pleth signal includes at least a first component associated with the operation of the patient's respiratory system and a second component associated with the patient's autonomic nervous system; and

a processor operated for processing the pleth signal to distinguish an effect associated with one of said first and second components from an effect associated with the other of said components, wherein said processor is operative for distinguishing said effect by determining first information related to a first signal defined by variations in blood pressure over time, determining second information related to a second signal defined by variations in heart rate over time, and using said first information and said second information to obtain third information related to a difference between said first signal and said second signal and for using said distinguished effect to monitor said physiological parameter.

26. (Original) An apparatus as set forth in Claim 25, further comprising at least one source for transmitting an optical signal relative to said patient such that said signal interacts with said blood of said patient; and

a detector system for detecting said transmittal optical signal and providing said pleth signal such that said pleth signal is reflective of said detective optical signal.

27. (Original) An apparatus as set forth in Claim 26, wherein said detector system comprises a sensor for receiving the transmitted optical signal and providing a sensor output reflective of said received optical signal and circuitry for processing said sensor output signal to provide said pleth signal.

28. (Currently Amended) An apparatus as set forth in Claim 26, wherein said at least one source is ~~operated for providing~~ operative to provide a first channel of said optical signal having a first spectral content and a second channel of said optical signal having a second spectral content different from said first spectral content.

29. (Original) An apparatus as set forth in Claim 25, wherein the processor is operative for distinguishing an effect associated with said first component and using said effect to monitor said patient's breathing.

30. Canceled.

31. (Currently Amended) An apparatus as set forth in Claim ~~30~~ 25, wherein said blood pressure is monitored by acquiring at least a portion of the pleth signal, filtering at least one component from the acquired signal portion, and determining information regarding a variation in blood volume over time related to the first and second components.

32. (Currently Amended) An apparatus as set forth in Claim ~~20~~ 25, wherein said heart rate is monitored by acquiring at least a pulsatile pleth signal and determining information regarding a variation in heart rate over time related to the first and second.

33. (Currently Amended) An apparatus as set forth in Claim 25, wherein said processor is operative ~~for distinguishing said effect by determining first information related to a first signal defined by variations in blood pressure over time, determining second information related to a second signal defined by variations in heart rate over time, and using said first information and said second information to obtain third information related to~~ to determine a phase difference between said first signal and said second signal.

34. (Original) An apparatus as set forth in Claim 33, wherein said processor is operative for using said identified phase difference to analyze said pleth signal so as to obtain information related to said first component.

35. (Currently Amended) A method as set forth in Claim 25, wherein said processor is operative to determine ~~substep of distinguishing comprises determining first information related to a first signal defined by variations in blood pressure over time, determining second information related to a second signal defined by variations in heart rate over time, and using said first information and said second information to obtain third information related to~~ a difference in waveform between said first signal and said second signal.

36. (Original) An apparatus as set forth in Claim 25, wherein said processor is operative for measuring said patient's respiration rate and providing an output indicative thereof.

37. (New) A method for use in noninvasively monitoring a physiological parameter of a patient, comprising the steps of:

obtaining a photoplethysmographic ("pleth") signal that is modulated based on interaction of a transmitted optical signal with blood of said patient, wherein said pleth signal includes at least a first component associated with the operation of the patient's respiratory system and a second component associated with the patient's autonomic nervous system;

processing said pleth signal relative to said first and second components;

distinguishing an effect associated with one of said first and second components from an effect associated with the other of said components, wherein said distinguishing comprises determining first information related to a first signal defined by variations in blood pressure over time, determining second information related to a second signal defined by variations in heart rate over time, and using said first information and said second information to obtain third information related to a difference between said first signal and said second signal; and

using said distinguished effect to monitor said physiological parameter.

38. (New) A method as set forth in Claim 37, wherein said first component relates to the patient's respiratory sinus arrhythmia.

39. (New) A method as set forth in Claim 37, wherein said second component relates to a Mayer Wave of said patient.

40. (New) A method as set forth in Claim 37, wherein said difference between said first signal and said second signal comprises a phase difference.

41. (New) A method as set forth in Claim 40, wherein said step of distinguishing further comprises using said identified phase difference to analyze said pleth signal so as to obtain information related to said first component.

42. (New) A method as set forth in Claim 37, wherein said difference between said first signal and said second signal comprises a waveform difference.

43. (New) A method as set forth in Claim 37, wherein said step of distinguishing comprises distinguishing an effect associated with said first component and said step of using comprises the step of monitoring said patient's breathing.

44. (New) A method as set forth in Claim 37, wherein monitoring said heart rate comprises by acquiring at least a pulsatile portion of the pleth signal and determining information regarding a variation in heart rate over time related to the first and second components.

45. (New) A method as set forth in Claim 37, wherein monitoring said heart rate comprises by acquiring at least a baseline portion of the pleth signal and determining information regarding a variation in heart rate over time related to the first and second components.

46. (New) A method as set forth in Claim 37, wherein monitoring comprises measuring said patient's respiration rate.

REMARKS

Claims 1-36 are pending in the application prior to entry of this amendment. Claims 1, 8, 9, 14, 18, 19, 25, 28, 31-33, and 35 and are being amended; Claims 3, 16 and 30 are canceled without prejudice; and Claims 37-46 are added.

In the April 11, 2003 Office Action, the Examiner objected to Claim 28. Claim 28 has been amended as suggested by the Examiner.

The Examiner also rejected Claims 1-13, 19 and 20 under 35 USC § 112 as being indefinite. In particular, the Examiner noted claims 1, 8, 9, 19 and 20 were written in improper method claim format. Appropriate correction has been made to these claims. Accordingly, Applicant submits that this rejection has been obviated.

The Examiner rejected Claims 1-4, 6, 7, 13-16, 18, 20, 24-27, 29, 30, 32 and 36 under 35 USC §102(b) as being anticipated by U.S. Patent 6,129,675 to Jay. The Examiner also rejected Claims 1-9, 13-20, 24-32 and 36 under 35 USC §102(b) as being anticipated by U.S. Patent 5,273036 to Kronberg et al. The noted claims include three Independent Claims (Claims 1, 14 and 25), each of which was rejected by both cited references. As set forth below, all the claims are believed to be allowable as presented and therefore, these rejections are respectfully traversed. Independent Claims 1 and 14 are first discussed below.

Independent Claim 1 is directed to a method for monitoring a physiological parameter of a patient. The method includes the steps of obtaining a pleth signal that includes at least a first respiratory component and a second Mayer wave component that is associated with a patient's autonomic nervous system. This pleth signal is processed to distinguish effects associated with the respiratory components from an effects associated with the Mayer wave components. A distinguished effect is utilized for monitoring a physiological parameter. For example, an effect

associated with the Mayer wave may be utilized to monitor, inter alia, hypertension, ventricular tachycardia and/or coronary artery disease. Alternatively, an effect associated with the patient's respiratory system may be utilized to monitor, for example, heart rate and/or pulse rate. The difficulty associated with monitoring physiological parameters based on an effect associated with a respiration component and/or Mayer wave component of a pleth signal is that these components can occur within overlapping frequency ranges. In this regard, the method of claim 1 allows for isolating these components such that an effect associated with these components may be identified for use in subsequent monitoring procedures. That is, effects of one component (i.e., the Mayer wave or the respiration) are isolated such that a particular physiological parameter can be more readily monitored.

Jay fails to recognize the existence of the Mayer wave or the desirability of isolating the Mayer wave components from respiratory system components in order to provide improved physiological monitoring. As presented, Jay provides a device and method for measuring pulsus paradoxus. As defined by Jay, the medical term pulsus paradoxus refers to a quantifiable exaggerated decrease in arterial blood pressure during inspiration. See Column 1 lines 19-22. To generate a pulsus paradoxus signal, Jay extracts from a pleth signal a first frequency component related to respiration and a second frequency component associated with pulse. See Column 3 lines 50-61. Jay correlates these components to generate the pulsus paradoxus signal. See Column 4 lines line 61-68. Jay fails to recognize that the first frequency component related to respiration may overlap with a frequency component related to the Mayer wave. Accordingly, Jay fails to provide a method for distinguishing between effects associated with the Mayer wave and effects associated with the respiratory component. Applicant submits that Jay fails to disclose or suggest the claimed subject matter of Claim 1 and respectfully requests this rejection be withdrawn.

Kronberg fails to recognize the existence of the Mayer wave and/or the desirability of isolating components associated with the Mayer wave in a pleth signal from respiratory components for monitoring purposes. As presented, Kronberg provides a method for monitoring a patient's respiration utilizing a pulse oximeter. However, Kronberg fails to recognize that Mayer wave components within the pleth signal may overlap with the respiratory components and thereby effect the accurate monitoring of such respiration. Accordingly, Applicant submits that the Kronberg fails to disclose or suggest the claimed subject matter and respectfully requests this rejection be withdrawn.

Independent claim 14 provides a method for monitoring a patient's respiration based on a base-line portion of a pleth signal. In this regard, an optical signal is transmitted relative to a patient such that the signal interacts with the blood of the patient. A detector system detects the transmitted optical signal and provides a pleth signal indicative of the detected optical signal, which includes at least a first respiratory component and a second Mayer wave component associated with the patient's autonomic nervous system. First, the pleth signal is processed to isolate a pulsatile pleth signal and a baseline signal. Secondly, the baseline signal is processed to distinguish an effect associated with the first component from effects associated with the second component. Effects associated with the Mayer wave may be distinguished from effects associated with the respiratory wave within the baseline pleth signal. Accordingly, the distinguish effect may be utilized to monitor a patient's breathing. The method of claim 14 recognizes that the baseline signal includes the respiratory component(s) and the Mayer wave component. Furthermore, the method of Claim 14 recognizes that these individual components may be more easily distinguished within the baseline signal than within the AC pleth signal or a combined pleth signal. Accordingly, enhanced monitoring of a patient's breathing may be provided.

As noted above, Jay fails to recognize the existence of the Mayer wave or the desirability of isolating the Mayer wave components from respiratory system components in order to provide improved physiological monitoring. Furthermore, Jay fails to disclose or suggest the isolation of a baseline portion of a pleth signal for use in monitoring a patient's breathing. Accordingly, Jay fails to disclose the subject matter of Claim 14 and Applicant respectfully requests that this rejection be withdrawn.

Kronberg fails to recognize the existence of the Mayer wave. Accordingly, Kronberg fails to recognize, inter alia, the use of a baseline portion of pleth signal to isolate respiratory components and Mayer wave components that may be utilized to monitor respiration. Accordingly, Applicant submits that the Kronberg fails to disclose or suggest the subject matter claimed in Claim 14 and respectfully requests this rejection be withdrawn.

Independent Claim 25 has been amended to generally include the content of Claim 33. Claim 33 previously depended from Claim 25. The Examiner indicated that Claim 33 would be allowable if presented in independent form. Therefore, Applicant submits that Claim 25 and all claims depending therefrom are allowable.

New Independent Claim 37 corresponds to Claim 1 rewritten to include the limitations of dependent Claim 10. As written, new Claim 37 does not recite the limitations set forth in previous dependent Claim 6, from which Claim 10 depended. Furthermore, applicant has removed the term phase from dependent claim 10. The term phase has been retained in new dependent claim 40. However, applicant respectfully submits that New claim 37 is allowable as presented.

Based upon the foregoing, Applicants believe that all pending claims are in condition for allowance and such disposition is respectfully requested. In the event that a telephone conversation

would further prosecution and/or expedite allowance, the Examiner is invited to contact the undersigned.

Respectfully submitted,

MARSH FISCHMANN & BREYFOGLE LLP

By: _____

Russell T. Manning, Esq.
Registration No. 51,260
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(720)562-5502

Date: October 21, 2003